

# Health-Chem Diagnostics, LLC

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## ONE STEP TORCH PANEL IgM TEST

### INTENDED USE

The **One Step TORCH IgM Test** is a panel of rapid qualitative lateral flow test designed for the qualitative detection of IgM antibodies to *Toxoplasma gondii* (TOXO), *Cytomegalovirus* (CMV), *Rubella*, *Herpes Simplex Virus (HSV-1 and HSV-2)* in human serum/plasma samples.

### SUMMARY AND CLINICAL SIGNIFICANCE for TOXO

*T. gondii* is an obligate intracellular protozoan parasite with a worldwide distribution (1,2). Serological data indicate that approximately 30% of the population of most industrialized nations is chronically infected with the organism (3). When a seronegative woman becomes infected with *T. gondii* during pregnancy, the organism is often transmitted across the placenta to the fetus (1,4). The severity of the infection in the fetus varies with the trimester during which the infection was acquired. Infection during pregnancy may lead to spontaneous abortion, stillbirth or overt diseases in the neonate.

Approximately 75% of congenitally infected newborns are symptomatic. However, nearly all children born with subclinical toxoplasmosis will develop adverse ocular or neurologic sequelae later in life (4,7). Approximately 80-85% develops chorioretinitis and some may also experience blindness or mental retardation.

A variety of serologic tests for antibodies to *T. gondii* have been used as an aid in diagnosis of acute infection and to assess previous exposure to the organism. The more widely used tests include the Sabin-Feldman dye test, direct agglutination, indirect hemagglutination, latex agglutination, indirect immunofluorescence, and ELISA (5,6).

### SUMMARY AND EXPLANATION OF THE TEST FOR CMV

Cytomegalovirus is a herpes virus and a leading biological factor causing congenital abnormalities and complications among those who receive massive blood transfusions and immunosuppressive therapy. About half of the number of pregnant women who contract a primary infection, spread the disease to their fetus. When acquired in-utero, the infection may cause mental retardation, blindness, and/or deafness.

Serological tests for detecting the presence of antibody to CMV can provide valuable information regarding the history of previous infection, diagnosis or active or recent infection, as well as in screening blood for transfusions in newborns and immuno-compromised recipients.

### SUMMARY AND EXPLANATION OF THE TEST FOR RUBELLA

Rubella is a herpes virus. Generally, rubella is considered a mild adolescence disease. However, a maternal infection could be transmitted through the placenta to the fetus, causing congenital rubella. Congenital rubella may result in chronic cardiac disease, growth retardation, hepatosplenomegaly, malformations and other severe anomalies. Children born asymptomatic may develop these abnormalities later in life.

To reduce the risk of such severe complications, accurate serological methods must be performed to determine the serologic status of childbearing aged women. The presence of rubella specific IgG in the bloodstream attests immunity to rubella. A woman tested to be non-immune can be educated on the availability of vaccination. An increase in rubella IgG denotes an acute infection and differentiates rubella from other exanthematous diseases. Expecting women with current rubella infection should be counseled on the consequences of congenital infection.

### SUMMARY AND EXPLANATION OF THE TEST FOR HSV-1 AND HSV-2 (Herpes Simplex Virus)

HSV-1 is usually associated with infection in oropharyngeal area and eyes, while HSV-2 causes mostly genital and neonatal infections (1,2), however, the tissue specificity is not absolute (3). HSV-2 can be isolated occasionally from the oropharynx and 5-10% of primary genital infections may be caused by HSV-1. Infants infected with HSV appear normal at birth, but almost invariably develop symptoms during the newborn period (1,4,5). Neonatal HSV infection may remain localized or become disseminated. Localized infection may involve one or a combination of sites. These are skin, eyes, mouth

or the central nervous system. Disseminated infection is manifested by pneumonitis, hepatitis, disseminated intravascular coagulopathy and encephalitis. Of the infants with neonatal HSV, about one half of those surviving will develop severe neurological or ocular sequelae.

A number of serological procedures have been developed to detect antibodies to HSV. These include complement fixation, indirect immunofluorescent antibody, plaque neutralization, and ELISA (2,4,6). Antibody of the IgM class is produced during the first 2-3 weeks of infection with HSV and exists only transiently in most patients. Serologic procedures, which measure the presence of IgM antibodies, help discriminate between primary and recurrent infections, since IgM antibodies is rarely found in recurrent infections.

High affinity IgG antibodies to HSV, if present in a sample, may interfere with the detection of IgM specific antibody (9). High affinity IgG antibody may preferentially bind to HSV-1 antigen leading to false negative IgM results. Also, rheumatoid factor, if present, along with antigen specific IgG, may bind to IgG causing false positive IgM results. Both problems can be eliminated by deactivating IgG in the sample before testing for IgM.

### Principles of the Procedure

The **One Step TORCH IgM Test** uses a sandwich immunoassay system and the innumochromatographic detection assay, to be performed in one assay. If TORCH antibody is present in the test sample in concentrations above the detection level, a labeled antibody-dye complex forms. This complex is then captured by antigen immobilized in the Test Zone ("T") of the membrane, producing a visible pink-rose color band on the membrane. The color intensity will depend on the concentration of TORCH antibody in the sample. However, a color band will always appear at the control zone (C).

### STORAGE AND STABILITY

1. Store the test kit as packaged at 2-30°C until time of use.
2. DO NOT FREEZE.
3. Do not use beyond the expiration date.

### PRECAUTIONS

1. For professional *In Vitro* Diagnostic use only.
2. Do not use after the expiration date.
3. Do not use reagents from different kits.
4. Store reagents 4-30°C. Do not freeze.
5. Devices should be kept dry in the resealable foil pouch with desiccant. Allow the strips and pouch to equilibrate to room temperature before opening the pouch to avoid condensation of moisture onto the strips. Always reseal the foil pouch after use.

6. Do not smoke, eat or drink in areas where testing is conducted.
7. Do not mouth pipette. Universal precautions should be practiced. PVC gloves and proper protective eyewear and clothing should be worn at time of testing. After the procedure, hands should be washed thoroughly.
8. Infectious specimens and non acid-containing spills should be wiped thoroughly with 5% sodium hypochlorite.
9. All waste materials should be properly disinfected before disposal. Liquid and solid wastes should be autoclaved for at least 1 hour at 121.5°C.
10. Once the assay has been started, all subsequent steps should be completed without interruption and within the recommended time limits.

### INSTRUCTIONS: SPECIMEN COLLECTION

The test can be performed on either serum or plasma. It is recommended that fresh samples be used if possible. If this is not possible, samples should be stored in a refrigerator (2-8°C) before being analyzed. For long term storage, specimens should be frozen at -20°C.

### MATERIALS PROVIDED

1. Test device
2. Developed Buffer solution in a dropper bottle
3. Package insert

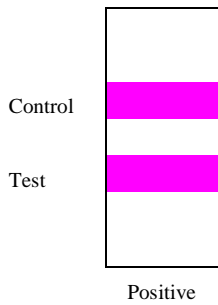
### ASSAY PROCEDURE

1. Read package insert carefully before testing. Allow the test devices, whole blood, serum or plasma to equilibrate to room temperature (15-30°C) prior to testing. Do not open packaging until ready to perform the assay.
2. Remove the test device from the foil pouch and use it as soon as possible.
3. Place the test device on a clean and level surface. Dispense 5 ul of specimen into buffer (between T line region and end edge of the view window). The T line region must be wet by the sample added.
4. After 30 seconds, add 3-4 drops of Buffer into each well.
5. Read Time: Torch-IgM Panel Test: 10 minutes

### INTERPRETATION OF RESULTS

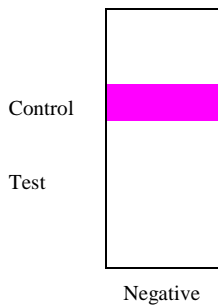
**Positive Result:** If there is a rose-pink color band in the control region (marked with a "C"), and a rose-pink color band in the test region (marked with a "T"), TORCH antibody is present and the specimen is positive.

### Single Device



**Negative Result:** The absence of a color band in the test region next to the letter “T” indicates the absence of any detectable TORCH antibody.

### Single Device

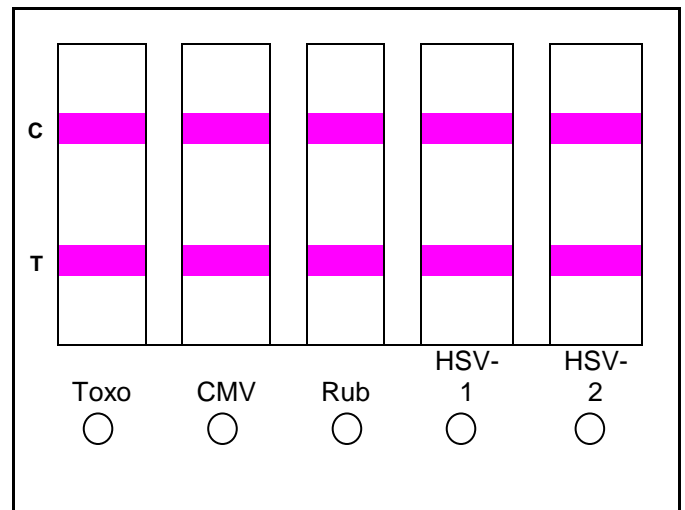


**Invalid Result:** If a color band does not appear in the control region “C”, the test results are invalid. The sample may have been added to the wrong window, or the Test Device may have deteriorated. This specimen should be retested using a new Test Device.

## LIMITATIONS OF PROCEDURE

1. Use fresh samples whenever possible. Frozen and thawed samples (especially repeatedly) contain particles that can block the membrane. This slows the flow of reagents and can lead to high background color, making the interpretation of results difficult. (See remarks on Frozen Specimens).
2. Optimal assay performance requires strict adherence to the assay procedure described in this insert sheet. Deviations may lead to aberrant results.
3. A repeatedly positive result in this test is presumptive evidence of the presence of antibodies to TORCH in the specimen. A negative result indicates the likely absence of detectable antibodies to TORCH in the specimen, but it does not exclude the possibility of exposure to or infection with TORCH.
4. False positive and negative results might be expected with a test kit. The proportions of false results will depend on the sensitivity and specificity of the test, and on the prevalence of TORCH antibody in the population to be screened.

### Five In One Device



### Clinical Data:

A clinical comparison study was performed between Torch ELISA and the HCD One-Step Test.

#### Expected Values and Cut-Off

The normal antibody titer for negative values assayed by ELISA is less than 0.25 O.D.

The cut-off of the ELISA test is 0.6 O.D.

The antibody level exceeding 0.6 O.D. suggests positive results.

### Comparison Study between Torch ELISA and HCD One-Step Test

ELISA	Cut off	Tested No.			Correlation	
		Neg	Pos	Neg	Pos	Neg
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TOXO						
IgG	<0.25	>0.6	28	24	100%	96%
IgM	<0.25	>0.6	26	18	100%	94%
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CMV						
IgG	<0.25	>0.6	28	24	100%	96%
IgM	<0.25	>0.6	28	24	100%	94%
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Rubella						
IgG	<0.25	>0.6	28	24	100%	96%
IgM	<0.25	>0.6	28	24	100%	95%
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HSV-1						
IgG	<0.25	>0.6	18	46	100%	98%
IgM	<0.25	>0.6	21	35	100%	97%
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HSV-2						
IgG	<0.25	>0.6	16	54	100%	98%
IgM	<0.25	>0.6	19	34	100%	97%
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